



FDA Regulation of Imported Foods in an Age of Globalization

Citation

FDA Regulation of Imported Foods in an Age of Globalization (2002 Third Year Paper)

Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8846760>

Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

Share Your Story

The Harvard community has made this article openly available.
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

FDA Regulation of Imported Foods in an Age of Globalization

Course Paper by M. William Schisa (Class of '02)

March 2002

Dedicated to the world's puppies.

ABSTRACT:

This essay will explore the intersection between the FDA's regulation of imported foods and the United States' obligations under the General Agreement on Tariffs and Trade (GATT) the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), and the Agreement on Technical Barriers to Trade (TBT Agreement), three of the foundational documents underlying the WTO system. I will argue that the FDA's import regime violates US trade obligations both by virtue of its use of a different standard for denying imported food access to the US market than for determining whether domestically produced food is fit for consumption and by virtue of the relatively informal manner in which FDA is able to exercise virtually limitless statutory authority over imported foods. Additionally, the essentially ad hoc determination of what imported food is inspected or detained, while not necessarily inconsistent with the WTO regime, is susceptible to abuses that could give rise to trade complaints.

As a result of improved transportation technology and reduced trade barriers, the United States today imports an unprecedented amount of food from the rest of the world. Yet the Food and Drug Administration, the body charged with ensuring the safety and suitability of that food for American consumers, is ill equipped to fulfill that mandate. While the amount of FDA-regulated food imported into the United States has increased substantially over the past decade, the resources that FDA has available to monitor food imports have largely remained constant. Perhaps more importantly, the FDA continues to rely on an import regulation scheme that is both inadequate to ensure the safety of food reaching the American people and at the same time arguably inconsistent with US obligations under the World Trade Organization.

This essay will explore the intersection between the FDA's regulation of imported foods and the United States' obligations under the General Agreement on Tariffs and Trade (GATT) the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), and the Agreement on Technical Barriers to Trade (TBT Agreement), three of the foundational documents underlying the WTO system. I will argue that the FDA's import regime violates US trade obligations both by virtue of its use of a different standard for denying imported food access to the US market than for determining whether domestically produced food is fit for consumption and by virtue of the relatively informal manner in which FDA is able to exercise virtually limitless statutory authority over imported foods. Additionally, the essentially ad hoc determination of what

imported food is inspected or detained, while not necessarily inconsistent with the WTO regime, is susceptible to abuses that could give rise to trade complaints. Nonetheless, in this area of regulation, US interests in promoting free trade should not take precedence over public health. The FDA should take steps pursuant to the SPS Agreement to negotiate agreements recognizing the equivalence of foreign food safety regimes, as such agreements reduce barriers to trade while at the same time conserving FDA resources. In many cases, however, such agreements will simply not be appropriate, because the foreign regulatory authority in question is simply unable to ensure an adequate level of food safety. In such cases, FDA has little choice but to rely on its current regime of targeted inspections and import alerts. In order to ensure that this system is as effective as possible, the FDA needs to treat imported food differently from its domestic equivalent, even if such differential treatment is a violation of US treaty obligations.

I. An Explosion in Food Imports

FDA-regulated food products make up a large percentage of the foreign trade of the United States. A recent study found that one quarter of products entering the United States were FDA-regulated food products. This amounts to nearly 2.25 million imported products.¹ Over the last decade, the amount of food imported by the United States has increased dramatically. In terms of food regulated by the FDA alone, the approximate value of food imported has nearly doubled, from \$23 billion in 1991 to \$41.2 billion in 2000.² The largest

¹Linda R. Horton, "Food From Developing Countries: Steps to Improve Compliance," 53 Food Drug L.J. 139, 140-1 (1998).

²Source: http://strategis.ic.gc.ca/sc_mrkti/tdst/engdoc/tr_homep.html. (visited 2/29/02). Dollar figures are in current year dollars. These numbers are by necessity approximate. FDA does not regulate all food imported into the United States. The United States Department of Agriculture regulates imports of meat and poultry. The trade statistics used here divide imports into categories that do not necessarily track this regulatory difference. The categories of goods included in this figure are:

1. Cereals
2. Products of the Milling Industry; Malt, Starches, Inulin and Wheat Gluten
3. Fats, Oils, Their Cleavage Products and Waxes
4. Meat, Fish and Seafood Preparations
5. Sugars and Sugar Confectionery
6. Cocoa and Cocoa Preparations
7. Preparations of Cereals, Flour, Starch or Milk (Including Bread and Pastry)

categories of imported food by value in 2000 were “Beverages, Spirits, and Vinegar,” and “Fish, Crustaceans, Molluscs, and Other Aquatic Invertebrates,” each of which accounted for over \$8 billion in imports. Also of note is the rapid growth in imports of prepared foods.³ This is particularly important to the FDA because such foods typically are intended for sale directly to US consumers, without any further processing in the US that can serve as an intervention point for regulators.⁴ Food is imported from over one hundred different countries.⁵ The ten largest exporters of food to the US by value are, in descending order: Canada, Mexico, Thailand, France, Italy, Chile, United Kingdom, the Netherlands, Brazil, and the People’s Republic of China.⁶ It is striking that half of these are developing states. In fact, over 40% of US food imports come from the developing world.⁷ These imports are of special concern to the FDA because food producers in developing countries often have difficulty in assuring adequate sanitation. Such countries may also be more vulnerable to outbreaks of pests or disease that might affect food safety.⁸

As seems typical with the FDA, the increasing scope of the agency’s duties has not been matched by a

8. Preparations of Vegetables, Fruit, Nuts or Other Parts of Plants
9. Miscellaneous Edible Preparations
- Beverages, Spirits and Vinegar
10. Fish, Crustaceans, Molluscs and Other Aquatic Invertebrates
11. Dairy Produce, Eggs, Honey and Other Similar Edible Products of Animal Origin
12. Edible Vegetables and Certain Roots and Tubers
13. Edible Fruits and Nuts
14. Coffee, Tea, Maté and Spices

³*Id.*

⁴See Horton, *supra* n. 1 at 140. See also trade statistics available at http://strategis.ic.gc.ca/sc_mrkti/tdst/engdoc/tr_homep.html.

⁵Source: http://strategis.ic.gc.ca/sc_mrkti/tdst/engdoc/tr_homep.html.

⁶Source: http://strategis.ic.gc.ca/sc_mrkti/tdst/engdoc/tr_homep.html. These ten countries accounted for approximately 60% of all imported food in 2000. Canada and Mexico accounted for half of this amount.

⁷Source: http://strategis.ic.gc.ca/sc_mrkti/tdst/engdoc/tr_homep.html. For lack of a better method, states are classified as “developing” if they are not members of the Organisation for Economic Cooperation and Development (OECD). The OECD is the “international organization of the industrialized, market-economy countries.” See <http://www.oecdwash.org/ABOUT/aboutmain.htm>. (visited 3/1/02).

⁸Horton, *supra* n.1 at 155-157. In fact, the rising amount of imported food has coincided with an increase in the incidence of diseases caused by food-born pathogens. See James R. Burke, “Comment: Warning: The Imported Food You are About to Consume May (Or May Not) Be Harmful to Your Health.” 15 J. Contemp H. L. & Pol’y 183, 183 (1998).

concurrent increase in agency resources. Although The Clinton Administration's Food Safety Initiative⁹ did result in some increased funding for import inspection activities, FDA remains unable to inspect more than a small portion of imported food products.¹⁰ The increased availability of imported food is potentially a tremendous boon to American consumers. If, however, the safety of this food cannot be guaranteed, those benefits may be overshadowed. It is thus essential for the FDA to find a way to deal with vastly increased quantities of imports without imposing undue burdens on those imports reaching the market.

II. Existing FDA Regulation of Food Imports

FDA's current import regime, however, was largely developed in a time where food imports were much less prevalent than they are today. It is uncertain whether it will prove up to the challenge of ensuring the safety of imported food in this age of easy transportation and low trade barriers. The statutory basis for FDA regulation of imported food is Section 801 of the Food, Drug and Cosmetic Act.¹¹ The relevant portions of the statute are as follows:

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony [...]. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, [...], (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, [...], then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations.¹²

⁹See <http://www.cfsan.fda.gov/~dms/fsibroch.html> (visited 2/28/02).

¹⁰See Burke, *supra* n. 8 at 192-194.

¹¹21 U.S.C. §381

The key element of the statutory language is the phrase “If it *appears* from the examination of such samples or otherwise.” This allows FDA to treat imported food in a fundamentally different way from its domestically produced equivalent. The FDCA prohibits the introduction of domestically produced food into interstate commerce only where such food is *actually* adulterated or misbranded.¹³ For imported food, the “mere appearance of adulteration is enough to compel refusal to admit.”¹⁴ There is no requirement that the food be actually adulterated, or that the FDA find as a fact that it is.¹⁵ In practice, the main effect of this differential treatment seems to be twofold. The different substantive standard allows FDA to prevent shipments of imported goods from entering the stream of commerce based either on the results of testing of a small sample of the shipment, or on general information about the importer or the country of origin. The statute also affords considerably fewer procedural protections to importers, whose products may be detained by FDA without a judicial condemnation proceeding.¹⁶ U.S. courts have not been troubled by this differential treatment.¹⁷ Typically this differential treatment is justified by practical necessity, namely the inability of FDA to effectively inspect foreign processing facilities.¹⁸ It should be noted that the court decisions blithely upholding this differential treatment all occurred prior to the 1994 Marrakesh Agreement establishing the World Trade Organization.¹⁹ Despite the fact that the FDA’s differential treatment of imported foods may violate US obligations to the WTO,²⁰ US courts are not permitted to strike down or alter their construction of statutes so as to render them consistent with the WTO treaties.²¹ Thus unless Congress decides to amend

¹³21 U.S.C. §342 (adulterated food); 21 U.S.C. §343 (misbranded food). See *Sugarman v. Forbragd* 267 F.Supp. 817, 823 (N.D.Cal.1967) (“Thus a food of domestic origin which *is* adulterated is subject to seizure and condemnation through the judicial process; the owner is entitled to a jury trial; and the Government must prove that the food *is in fact* adulterated.”)(emphasis in original).

¹⁴*Sugarman* 267 F.Supp. at 824.

¹⁵*Id.* at 824.

¹⁶*Sugarman* 267 F. Supp at 824.

¹⁷See *Continental Seafoods, Inc. v. Scwheiker* 674 F.2d 38, n.10 (D.C.Cir.1982) (Noting FDA’s “long established authority to treat imported goods differently from domestic ones”).

¹⁸*Id.* at n. 10.

¹⁹Agreement Establishing the World Trade Organization, April 15, 1994. http://www.wto.org/english/docs_e/legal_e/final_e.htm#wtoagreement (visited 3/2).

²⁰See Part III, *infra*.

²¹The Uruguay Round Agreements Act (19 U.S.C. §3501 *et seq.*) expressly provides that “[n]o provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law

the FDCA, FDA will retain broad statutory authorization to exercise essentially plenary power over imports. FDA's broad statutory authority, however, is cabined in two important respects. First, the agency's persistent lack of adequate resources practically limits its monitoring of food imports. Second, FDA has established procedures under which it exercises the broad power and discretion granted it by Congress. This combination of practical and self-imposed limitations means that, despite FDA's broad powers, its actual ability to monitor imported food is quite modest. When an imported food product enters the United States, the importer or its agent is required to file entry documents with the U.S. Customs service.²² Customs flags imported articles subject to FDA regulation in order to bring them to FDA's attention.²³ For such articles, the importer is required to provide additional information, including an FDA product code, manufacturer identification codes for the foreign manufacturers and shippers, and the actual country of origin, which may differ from the country of origin for customs purposes.²⁴ The customs documents are then screened electronically by FDA's Operational and Administrative System for Import Support (OASIS) or manually by FDA employees.²⁵ At that point, FDA can take a number of actions. In most cases, the FDA takes no action, and issues a "May Proceed Notice" to Customs.²⁶ At that point, the product is released for entry into commerce in the United States. Permitting a product's importation does not preclude FDA from taking action with respect to the product in the future.²⁷

of the United States will have effect." 19 U.S.C. §3512(a)(1). Also, the entry of the United States into the WTO did not serve to "amend or modify any law of the United States, including any law relating to [...] the protection of human, animal, or plant life or health." 19 U.S.C. §3512(a)(2)(A)(i).

²²FDA Import Procedures, <http://vm.cfsan.fda.gov/~lrd/import.txt> (visited 2/26/02). These documents, which now are filed and processed electronically via Customs' Automated Commercial System, include a variety of information, including the product's "entry number, entry date, importer identification, port of entry, vessel/voyage information, filer identification, Harmonized Tariff Schedule (HTS) code(s) for product described in importing documents (tariff code), information on foreign shipper, country of origin, quantity, and value." FDA Regulatory Procedure Manual, Ch.9 Subchapter Import Procedures. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9imp.html (visited 2/26/02).

²³FDA Regulatory Procedure Manual, Ch.9, Subchapter Import Procedures. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9imp.html (visited 2/26/02).

²⁴*Id.*

²⁵*Id.* For a description of the technical specifications of OASIS, see <http://www.fda.gov/ora/import/oasis/home-page.html> (visited 3/05/02).

²⁶FDA Import Procedures, <http://vm.cfsan.fda.gov/~lrd/import.txt> (visited 2/26/02).

²⁷FDA Regulatory Procedure Manual, Ch.9 Subchapter Import Procedures. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9imp.html (visited 2/26/02).

In other cases, FDA may require examination of a sample before admitting a product shipment. The decision to collect and examine a sample is based on:

1.

The nature of the product

2. FDA priorities, and

3. Past history of the commodity²⁸

If FDA decides to collect a sample, the owner or consignee of the shipment is given notice of the sampling and is required to hold the product pending the outcome of laboratory analysis.²⁹ Based on this testing, FDA will either determine that the product is in compliance with FDA regulations and permit its entry, or determine that it appears to be adulterated, misbranded, or otherwise in violation of the FDCA.³⁰ Should FDA determine the latter, a Notice of Detention and Hearing is issued to the importer.³¹ The Notice is required to contain a sufficiently detailed description of the alleged violation(s) for the importer to understand and reply to the allegations.³²

Upon receipt of the Notice of Detention and Hearing, the importer has ten working days to respond to FDA's allegation. The importer is entitled to an informal hearing before FDA, and has the right to introduce evidence and written or oral testimony as to the admissibility of the shipment.³³ The importer may also seek

²⁸FDA Import Procedures, <http://vm.cfsan.fda.gov/~lrd/import.txt> (visited 2/26/02).

²⁹FDA Office of Regulatory Affairs Import Program System Information, http://www.fda.gov/ora/import/ora_import_system.html (visited 2/26/02).

³⁰FDA Import Procedures, <http://vm.cfsan.fda.gov/~lrd/import.txt> (visited 2/26/02).

³¹21 C.F.R. 1.94.

³²FDA Regulatory Procedure Manual, Ch.9 Subchapter Detention and Hearing. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9det.html (visited 2/26/02).

³³FDA Regulatory Procedure Manual, Ch.9 Subchapter Import Procedures. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9imp.html (visited 2/26/02).

to demonstrate that the product can be brought into compliance with FDA requirements, typically through re-labeling. This hearing “is the importer’s only opportunity to present a defense of the importation and/or to present evidence as to how the shipment may be made eligible for entry.”³⁴ Following the hearing the FDA will either determine the shipment to be in compliance with the FDCA and permit it to be imported, determine that it is not in compliance, but authorize the importer to attempt to bring it into compliance, or determine that it is irredeemably non-compliant, and refuse its admission. Articles that are refused admission must be exported under FDA supervision within 90 days or destroyed.³⁵ FDA’s determination of the admissibility of imports is *not* subject to judicial review, as it is “committed to agency discretion by law.”³⁶ Thus judicial review is precluded by the Administrative Procedures Act.³⁷

There is one additional action that FDA may take with regard to imported food. The FDCA authorizes FDA to refuse admission to imported products if “it appears from the examination of [...] samples *or otherwise*” that the product is in violation of the Act.³⁸ In certain circumstances, FDA has interpreted that language to allow it to detain certain products without physical examination (DWPE).³⁹ Typically, DWPE of shipments from a particular importer or country is appropriate where “there exists a history of the importation of violative products, or products that may appear violative, or when other information indicates that future entries may appear violative.”⁴⁰ The FDA Regulatory Procedures Manual offers detailed guidance on the specific circumstances under which DWPE is appropriate.⁴¹ Any regional FDA office may recommend

³⁴FDA Import Procedures, <http://vm.cfsan.fda.gov/~lrd/import.txt> (visited 2/26/02).

³⁵FDA Regulatory Procedure Manual, Ch.9 Subchapter Detention and Hearing. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9det.html (visited 2/26/02).

³⁶*Sugarman*, 267 F.Supp at 823.

³⁷5 U.S.C. §701(a)(2).

³⁸21 U.S.C. §381(a). (emphasis added).

³⁹This process was formerly known as “automatic detention.”

⁴⁰FDA Regulatory Procedure Manual, Ch.9 Subchapter Automatic Detention. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html (visited 2/26/02). Generally this will be because of a pattern of past violations, the result of an on-site inspection in a foreign country, or because of environmental factors calling into question the safety of food from a particular area.

⁴¹*See id*, particularly the Sections entitled “Recommendations Based on One Violative Sample,” “Recommendations Based on Information and Historical Date,” “Recommendation Based on Multiple Samples,” “Automatic Detention of Importers’ Entries,” and “Recommendations Based on Establishment Inspection.”

DWPE, although the final decision on the issue rests with the FDA Division of Import Operations and Policy (DIOP).⁴² Where it determines that DWPE is called for, DIOP will issue an Import Alert directing regional FDA offices to detain the product in question.⁴³

The adequacy of the procedure by which FDA issues an Import Alert has been questioned in a number of court decisions. In *Bellarno v. Klug*, 678 F.Supp. 410 (E.D.N.Y.1988), a Federal District court invalidated an Import Alert, holding that FDA Import Alerts instructing field operatives to automatically detain certain products were “legislative rules.”⁴⁴ As a result, the FDA is required to conduct informal rulemaking procedures set out in the Administrative Procedure Act⁴⁵ prior to the issuance of such an alert.⁴⁶ The *Bellarno* Court invalidated the import alert because of FDA’s failure to follow the required procedures.⁴⁷ Several other courts have similarly found problems with FDA’s issuance of import alerts.⁴⁸ FDA, however, continues to take the position that it need not conduct a rule-making procedure prior to placing a product on automatic detention.⁴⁹ FDA does, however, give importers the opportunity to present evidence to prove that their products should no longer be detained without examination. The standards for removing a manufacturer, product, or shipper from automatic detention are quite high, however.⁵⁰

⁴²FDA Regulatory Procedure Manual, Ch.9 Subchapter Automatic Detention. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html (visited 2/26/02).

⁴³FDA Regulatory Procedure Manual, Ch.9 Subchapter Import Information Directives. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9dirs.html (visited 2/26/02).

⁴⁴*Bellarno*, 678 F.Supp. at 416.

⁴⁵U.S.C.§553. The APA requires agencies to give adequate notice of proposed rules, and give interested parties an opportunity to comment.

⁴⁶*Bellarno*, 678 F.Supp. at 412.

⁴⁷*Id.* at 416.

⁴⁸*See* Peter Barton Hutt & Richard A. Merrill, eds., *Food and Drug Law: Cases and Materials* (2d. ed. 1991) 1087. All of these cases were decided at the District Court level.

⁴⁹FDA Regulatory Procedure Manual, Ch.9 Subchapter Import Information Directives. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9dirs.html (visited 2/26/02).

⁵⁰FDA Regulatory Procedure Manual, Ch.9 Subchapter Automatic Detention. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html (visited 2/26/02). For example, an importer who has a single product on automatic detention, and who is a first time violator, must provide evidence that its last five commercial shipments have been in full compliance with the FDCA.

III. The WTO Framework

A. General Overview

The FDA's system for dealing with imports evolved in a radically different world than the one we live in today. Until the birth of the World Trade Organization, the international trade system was largely unconcerned with measures that countries took to protect the health of their citizens, including food safety laws.⁵¹ The WTO changed all this. The member states of the WTO committed themselves not only to an unprecedented reduction in traditional trade barriers such as tariffs and quotas, but also to eliminating trade barriers that might result from domestic regulation. Subject to limited exceptions, member-states agreed to regulate imported products in the same manner as like domestic products.⁵² In the area of food safety, in particular, it was feared that measures with a disguised protectionist purpose might become increasingly popular. Agricultural products traditionally have been the beneficiaries of tariffs and quotas, and as those protections diminished in the new trade regime, it was feared that agricultural interests, particularly in the richer developed countries, would seek to impose stringent food safety requirements that exporters might not be able to meet.⁵³ The result of these fears was the Agreement on Sanitary and Phytosanitary Measures, probably the most ambitious and revolutionary multilateral trade agreement to date. In addition to incorporating the non-discrimination principle that is at the heart of the global trading system, the SPS Agreement also binds states to base non-discriminatory public health measures on sound science. The SPS agreement is thus potentially the primary international constraint on the FDA's regulation of food.⁵⁴ FDA

⁵¹Hutt & Merrill, *supra* n. 48 at 1088.

⁵²General Agreement on Tariffs and Trade III:4, October 13, 1947. [GATT]. http://www.wto.org/english/docs_e/legal_e/final_e.htm (visited 2/26/02).

⁵³See Understanding the Agreement on Sanitary and Phytosanitary Measures, http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm (visited 2/26/02). An example of this is the EU's ban on the import of beef containing certain hormones typically used to promote growth in cattle, despite the fact that there is no evidence that those hormones constitute a health risk. Oddly enough, those hormones are widely used in beef production outside of Europe, but not by European cattle farmers. The WTO Appellate Body has found the EU ban to be in violation of the Agreement on Sanitary and Phytosanitary Measures. *See generally* EU-Measures Concerning Meat and Meat Products AB-1997-4. Report of the Appellate Body (1997).

⁵⁴As yet, no FDA regulation has been challenged as violating either the SPS Agreement, TBT Agreement, or GATT. European trade officials, however, have asserted that FDA's nutrition labeling requirements are an illegal trade barrier. *See* Bruce A.

regulations relating to economic adulteration of food and nutrition labeling may additionally be within the ambit of the Agreement on Technical Barriers to Trade, which requires that such regulations be non-discriminatory and no more trade-restrictive than necessary to achieve their desired end.⁵⁵ The final major change made by the WTO regime was in the area of dispute resolution. Under the old trade regime, the General Agreement on Tariffs and Trade, disputes could be referred to panels of experts for adjudication, but the panel's decision was only binding if it was adopted by a unanimous vote of all signatories, including the state that lost the panel decision.⁵⁶ Under the WTO, the outcome of the dispute resolution process has become binding on the states, except where the member states unanimously reject a decision.⁵⁷

B. GATT

The General Agreement on Tariffs and Trade (GATT) is the cornerstone of the WTO regime. At its heart are two fundamental principles: Most-favored Nation status (MFN) and National Treatment (NT). The MFN principle is codified in Article I, paragraph 1 of the GATT, which states:

Silverglade, The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade? 55 Food Drug L.J. 517, 520 (2000). One commentator has also suggested that the Food Quality Protection Act of 1996 might violate the SPS agreement. See Edward M. McDonald, The Food Quality Protection Act of 1996: By Removing Chemical Irritants from Our Environment Will It Generate Trade Irritants to Replace Them? 25 Wm. & Mary L. & Pol'y Rev. 749 (2001).

⁵⁵Agreement on Technical Barriers to Trade, April 15, 1994. [TBT]. http://www.wto.org/english/docs_e/legal_e/final_e.htm (visited 2/26/02).

⁵⁶See Robert E. Hudec, The New WTO Dispute Settlement Procedure: An Overview of the First Three Years, 8 Minn. J. Global Trade 1, 9 (1999).

⁵⁷Understanding On the Rules and Procedures Governing Disputes 17:4, April 15, 1994. http://www.wto.org/english/docs_e/legal_e/final_e.htm (visited 2/26/02).

With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with importation and exportation, and with respect to all matters referred to in paragraphs 2 and 4 of Article III⁵⁸, any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.⁵⁹

With respect to FDA regulation of food imports, this provision requires FDA not to unjustifiably discriminate among like products based solely on their country of origin. Such discrimination does not seem particularly likely, but given the limited ability of FDA to actually inspect imports, and the essentially ad hoc way in which FDA determines which shipments to inspect, it is conceivable that some pattern of discrimination might emerge that would be actionable under this portion of the treaty. Such discrimination, however, would more than likely be justified under Article XX of the GATT.⁶⁰

Potentially more troublesome for FDA, however, is the national treatment requirement. Article III, paragraph 4 of the GATT states:

The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.⁶¹

FDA regulation of imports would seem to squarely violate this provision. FDA applies a different substantive standard to imported and domestic foods, and additionally provides fewer procedural safeguards when taking action against imported rather than domestic foods.⁶² Thus, for example, a head of lettuce from Chile and one grown in California are regulated quite differently. This is *prima facie* illegal under Article III.

⁶⁰ See discussion of Art. XX, *infra*.

⁶² See Part II., *supra*.

A number of important states have argued that Article III of the GATT should be read to incorporate an “aims and effects” test, which would only invalidate domestic taxes and regulations where they are found to have a disguised protectionist purpose.⁶³ Regulations that are legitimately intended to, for example, ensure food safety would thus not violate Art. III:4, even if they incidentally resulted in differential treatment between domestic and imported products. Put another way, this test would permit states to define “like” products in terms other than physical characteristics or consumer end-use. If, for example, Chilean lettuce contained potentially dangerous pesticide residues not present in Californian lettuce, it would be permissible for the United States to regulate Chilean and Californian lettuce differently—the different pesticide residues would cause the two types of lettuce not to be like products. The WTO Appellate Body⁶⁴ has flatly rejected this reasoning, holding that like products are to be defined in terms of consumer end-use alone.⁶⁵ Regardless of the purpose of a particular regulation, if it treats similar imported and domestic products differently, it is in violation of Art. III: 4 of the GATT.

Even if a regulatory measure violates Art. III:4, it may nonetheless be permissible under the GATT. The GATT recognizes that states have many legitimate regulatory goals that may require deviation from strict observance of the national treatment or MFN principles. Thus Article XX of GATT provides for a series of ten exceptions to those principles. The relevant text is:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

[...]

⁶³See Japan – Taxes on Alcoholic Beverages, AB-1996-2, 1996 WTO DS LEXIS 5 (1996) (argument made by Japan), European Communities – Regime for the Importation, Sale, and Distribution of Bananas, AB-1997-3, 1997 WTO DS LEXIS 10 (1996) (argument made by EC).

⁶⁴The Appellate Body is a permanent adjudicatory body with appellate jurisdiction over trade disputes brought under the WTO agreements. Disputes are brought in the first instance before *ad hoc* panels of experts in international trade law.

⁶⁵Japan – Taxes on Alcoholic Beverages, AB-1996-2, 1996 WTO DS LEXIS 5, *62-66. (1996).

(b) necessary to protect human, animal or plant life or health;

[...]

(d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to [...]the prevention of deceptive practices;⁶⁶

Analysis under Article XX is bifurcated. The WTO Panel must first determine whether the measure at issue falls within one of the enumerated exceptions. If it does, the Panel must go on to determine whether the measure is consistent with the Article's *chapeau*, that is, whether it constitutes either arbitrary or unjustifiable discrimination, or a disguised restriction on international trade.⁶⁷

If the FDA's import regime were challenged as violative of Art. III:4 of GATT, the United States would likely have to concede a *prima facie* violation, and argue that the import regime is justifiable under the provisions of Art. XX. With respect to Article XX(b), the United States would argue that, because of its inability to conduct adequate on-site inspections in foreign countries, it needs to apply a lower threshold of violation on imported foods in order to ensure the safety of imported foods. Of course, this justification would only apply to the FDA regulation of imports to ensure compliance with FDA regulations relating to food safety. FDA regulation of imports to enforce federal law relating to economic adulteration, misbranding, and other non-health related areas would have to fall under the catch-all provision of Article XX(d). The US argument under Article XX(d) would be that the FDCA is a law not inconsistent with the other provisions of the WTO, and that FDA's inability to conduct on-site inspections abroad makes differential treatment of imported goods necessary to secure compliance with all of the provisions of the FDCA.

In both cases, the success or failure of the US argument would turn on the meaning of the word "necessary." The WTO Appellate Body has articulated the standard for necessity in the context of Article XX(b) as follows:

⁶⁷United States – Standards for Reformulated and Conventional Gasoline, AB 1996-1, 1996 WTO DS LEXIS 1, *46 (1996).

[I]mport restrictions [...] could be considered to be necessary in terms of Article XX(b) only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which [the member state] could reasonably be expected to employ to achieve its health policy objectives.⁶⁸

The issue of whether an alternative measure would in fact be reasonably available is decided on a case-by-case basis, and involves balancing a number of factors.⁶⁹ In cases involving Article XX(b), the determinative factor will often be the importance of the value that is protected by the measure. Because the protection of human life and health is both “vital and important to the highest degree,” it is easier for a WTO panel to “accept as necessary measures designed to achieve [that] end.”⁷⁰ Unless the complaining state can propose a measure that would clearly provide the same level of overall health protection, and at the same time be less inconsistent with the GATT, a WTO panel is likely to uphold the measure as justified under XX(b). The FDA import regime seems likely to pass muster under this standard. Although the present FDA system is imperfect at best, any move to treat imported foods more like domestic foods would likely diminish FDA’s ability to prevent unsafe imported food from reaching the American consumer.

The Appellate Body’s treatment of necessity under Article XX(d) closely mirrors its Article XX(b) analysis. The key question remains whether there is an alternative measure reasonably available to the state that would be less inconsistent with the GATT than the measure it is seeking to justify.⁷¹ This requires a case-by-case balancing approach, with three main factors to consider:

[the] contribution made by the compliance measure to the enforcement of the law or regulation at issue, the importance of the common interests or values protected by that law or regulation, and the accompanying impact of the law or regulation on imports or exports.⁷²

Article XX(d) covers measures designed to achieve a wide variety of goals, so the relative importance of each of these factors may vary according to the measure at issue. In the case of the FDA import regime,

⁶⁹*Id.* at *155.

⁷⁰*Id.* at 156.

⁷¹Korea – Measures Affecting Imports of Fresh, Chilled, and Frozen Beef, AB-2000-8, 2000 WTO-DS-LEXIS 36, *118 (2000).

these factors would again seem to weigh in favor of justification. The FDCA clearly protects very important interests and values. Even if the economic and consumer interests protected by the FDCA are considered less important than the health and safety interests, the FDA's monitoring of imports necessarily must consider both of these aspects. It would be an administrative nightmare for the FDA to have to deal with two separate import regimes, one for dealing with potentially unsafe food, and one for dealing with all other violations of the FDCA. Because of the difficulty of disaggregating the two aspects of FDA enforcement, and the paramount importance of FDA's safety mission, to the extent that the FDA import regime is necessary in the sense required by Article XX(b), it would also have to be necessary under Article XX(d). The one possible exception to this might be in the area of automatic detention. This draconian sanction could be seen by a WTO panel as a disproportionately trade restrictive response if it were widely used for reasons other than the protection of consumer health. FDA's internal policy with regard to automatic detention, however, seems to limit its use to cases of suspected food safety problems, so this issue is unlikely to arise.⁷³ Even where a WTO panel finds a measure to be justified under one of the enumerated exceptions in Article XX, that measure may still violate the GATT if it does not conform to the additional requirement of the *chapeau* of Article XX that "such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade."⁷⁴ The Appellate Body treated the *chapeau* as containing three distinct prohibitions: against arbitrary discrimination, against unjustifiable discrimination, and against disguised restrictions on international trade.⁷⁵ The third prohibition, against disguised restrictions on international trade, can be dealt with summarily. It is essentially a requirement that the measure be no more trade

⁷³FDA Regulatory Procedure Manual, Ch.9 Subchapter Automatic Detention. (revised May 12, 1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html. (visited 2/26/02).

⁷⁴GATT XX, October 13, 1947. http://www.wto.org/english/docs_e/legal_e/final_e.htm (visited 2/26/02).

⁷⁵United States – Import Prohibition of Certain Shrimp and Shrimp Products, AB-1998-4, 1998 WTO DS LEXIS 13, *135 (1998).

restrictive than necessary to achieve its desired end.⁷⁶ If a measure is found to be “necessary” under Article XX(b) or XX(d), it will also satisfy this portion of the chapeau. Thus, assuming the FDA import regime falls within one of these exceptions, it will not be considered a “disguised restriction” on trade.

The discrimination provisions are more problematic for FDA. There are three elements of this part of the *chapeau*. The measure must result in *discrimination* between countries *where the same conditions prevail*, and that discrimination must be either *arbitrary* or *unjustifiable*.⁷⁷ The FDA’s import regime is clearly discriminatory, as the Appellate Body has interpreted the phrase “discrimination between countries” to apply not only to discrimination between different foreign countries, but also to discrimination between foreign countries and the country imposing the measure.⁷⁸ Whether that discrimination is between countries where the same conditions prevail is a much harder question. Many of the states from which the United States imports food, particularly those in the developing world, have a much lower level of basic sanitation than the US. Others are susceptible to plant or animal pests or diseases that are not prevalent in the United States. Nonetheless, the FDA treats *all* imports differently from domestically produced food, not just those from countries where conditions are different from the United States. It would be hard to characterize Canada, the top exporter of food to the United States, as a country where different conditions prevail.

The question thus becomes whether FDA’s discrimination is either arbitrary or unjustifiable. The US has a strong argument that the substantive aspect of the discrimination is neither arbitrary nor unjustifi-

⁷⁶United States – Standards for Reformulated and Conventional Gasoline, AB 1996-1, 1996 WTO DS LEXIS 1, *53-4 (1996).

⁷⁷The Appellate Body treats arbitrary discrimination and unjustifiable discrimination as separate violations of the *chapeau*, but does not offer any principled basis for distinguishing between the two. In the *United States – Shrimp* case cited above, the AB found the US to unjustifiably discriminate by virtue of its refusal to certify countries as “turtle-friendly” unless they adopted exactly the same regulatory scheme as the US, and because the US pursued turtle-conservation agreements with some countries, but not with others. The US was found to arbitrarily discriminate because the informal nature of its turtle conservation certification process lacked adequate procedural safeguards. The AB fails to explain why the former discrimination was “unjustifiable” and the latter “arbitrary,” or how one might apply the distinction between the two in other cases.

⁷⁸United States – Standards for Reformulated and Conventional Gasoline, AB 1996-1, 1996 WTO DS LEXIS 1, *53-4 (1996).

able. Given the inability of the United States to supervise and control the conditions under which foreign food is produced, allowing FDA to take action against imported food based on the mere appearance of adulteration is a sensible response. The procedural aspect of the discrimination is more troublesome. In the *United States – Shrimp* case, the Appellate Body found a US law prohibiting the import of shrimp from countries unless the US State Department certified that their shrimping practices did not unduly endanger sea turtles to be in violation of the *chapeau* of Article XX. Among the problems the Appellate Body had with the US measure was that the certification process lacked adequate procedural safeguards.

⁷⁹The FDA import regime does not suffer from many of the defects of the shrimp certification process. FDA does provide notice to importers whose products are

Other concerns expressed by the Appellate Body about the turtle certification regime do apply to the FDA import regime, however. In particular, the Appellate body criticized the fact that no procedure existed for review of or appeal from an adverse certification decision.⁸¹ This is also the case with an FDA decision to deny a product entry. It is uncertain whether that alone would be enough to characterize FDA's behavior as arbitrary. The Appellate Body has noted that "rigorous compliance with the fundamental requirements of due process should be required in the application and administration of a measure which purports to be an exception to the treaty obligations of the Member imposing the measure and which effectively results in a suspension pro hac vice of the treaty rights of other Members."⁸² Given this strong language, the lack of judicial review of FDA's import decisions could very well constitute a case of arbitrary or unjustifiable discrimination. Additionally, there does not seem to be any reason why more stringent procedural safeguards

⁷⁹United States – Import Prohibition of Certain Shrimp and Shrimp Products, AB-1998-4, 1998 WTO DS LEXIS 13, *178-179 (1998).

⁸⁰See generally FDA Regulatory Procedure Manual, Ch.9 Subchapter Detention and Hearing. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9det.html (visited 2/26/02), FDA Regulatory Procedure Manual, Ch.9 Subchapter Automatic Detention. (revised May 12,1998) http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html. (visited 2/26/02). In contrast, the turtle certification process was completely informal, did not provide any opportunity to be heard, and countries did not receive specific notification of whether their certification request was approved or denied. See United States – Import Prohibition of Certain Shrimp and Shrimp Products, AB-1998-4, 1998 WTO DS LEXIS 13, *177-178 (1998).

⁸¹United States – Import Prohibition of Certain Shrimp and Shrimp Products, AB-1998-4, 1998 WTO DS LEXIS 13, *178 (1998).

⁸²*Id.* At *179.

would be inconsistent with the FDA's mission to ensure the safety of food imports. The US might argue that because of FDA's scarce resources, the prospect of litigation over its decisions on imports would deter it from using its power to deny potentially harmful products access to the US market. The Appellate Body would most likely not be sympathetic to such an argument. Administrative inconvenience alone cannot justify discrimination.⁸³ Given the need of food producers, whether foreign or domestic, to establish cooperative working relationships with FDA, it seems unlikely that many FDA decisions on imports would be appealed, particularly given the extreme solicitude granted the FDA in US Courts. Additionally, in the case of automatic detention, a competent US authority has determined that the FDA is not only able to, but also required to adhere to more stringent procedural safeguards.⁸⁴ Thus it seems likely that under the GATT, the laxer procedural standards applied by FDA to imported foods are in violation of Article III:4, and not justified under Article XX.

C. The SPS Agreement

Even if the FDA food import regime is not in violation of GATT, the Agreement on Sanitary and Phytosanitary Measures imposes additional requirements with which FDA must comply. The SPS agreement applies to all sanitary and phytosanitary measures, which are defined as:

Any measure applied:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

⁸³United States – Standards for Reformulated and Conventional Gasoline, AB 1996-1, 1996 WTO DS LEXIS 1,*56-60.

⁸⁴See *supra* n.44 and accompanying text.

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.⁸⁵

Measures that fall within the ambit of the SPS Agreement will also typically be the sorts of measures that countries would try to justify under Article XX(b) of GATT. The SPS Agreement explicitly recognizes this. Measures that satisfy the requirements of the SPS Agreement are thus presumed to fall within the Article XX(b) exception.⁸⁶ The requirements of the *chapeau* of Article XX are also incorporated by the SPS Agreement.⁸⁷ Thus the above analysis of the legality of the FDA import regime under the GATT is equally valid under the SPS Agreement. The SPS Agreement, however, imposes additional requirements beyond those of the GATT. In summary form, states are required to base sanitary measures on scientific risk assessment principles. They are additionally encouraged to base domestic measures on international standards, where such standards exist. Sanitary measures that are based on international standards are presumptively in compliance with the Agreement. Deviations from international standards are permitted, but states are required to justify such deviations with scientific evidence that the international standards would not achieve the level of health protection that state feels is appropriate.⁸⁸ These requirements have generated substantial controversy, and potentially affect a great deal of what FDA does. For the purposes of this essay, however, they are not particularly important, as they relate more to the substantive content of FDA regulations than to the procedures by which FDA determines whether imported food complies with

⁸⁶SPS Agreement 2:4.

⁸⁷SPS Agreement 2:3.

⁸⁸See Understanding the SPS Agreement, http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm (visited 2/26/02).

those regulations.

The SPS Agreement does, however, explicitly address “control, approval, and inspection procedures,” such as the FDA import regime. Annex C of the agreement establishes a series of rules governing such procedures, and Article 8 of the treaty makes compliance with those rules mandatory.⁸⁹ Annex C provides, in relevant part, that:

Members shall ensure, with respect to any procedure to check and ensure the fulfillment of sanitary or phytosanitary measures, that:

(a) such procedures are undertaken and completed without undue delay and in no less favorable manner for imported products than for like domestic products...⁹⁰

The annex imposes a number of additional requirements as well, but there is no need to go beyond (a). The FDA import regime clearly violates this requirement, as it is clear that imported products are treated much less favorably than like domestic products. There is nothing in the language of the SPS Agreement that would seem to permit an exception to this rule, and it is highly doubtful that a WTO panel or the Appellate Body could be convinced to read an exception into the treaty against its plain language.

D. The TBT Agreement

The SPS Agreement is not the only specialized agreement that constrains FDA regulation of imported foods. FDA’s mission is not limited to the protection of public health; it also enforces laws whose primary aim is consumer protection. The requirement of nutrition labelling, for example, is not directly related to food safety, but rather is primarily intended to empower consumers to make informed choices about their diets. Additionally, FDA enforcement of filth tolerance levels and food identity standards is primarily for the

⁸⁹SPS Agreement 8.

purpose of protecting consumers from economic, rather than physical harm. These sorts of FDA regulations fall outside the ambit of the SPS Agreement, but will often be subject to the requirements imposed by the Agreement on Technical Barriers to Trade. The TBT Agreement applies to all “technical regulations,” which are defined as:

Document[s] which [lay] down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.⁹¹

The TBT Agreement applies to both industrial and agricultural products, although it explicitly does not apply to sanitary and phytosanitary regulations.⁹² FDA nutrition labelling requirements, filth tolerances, and food identity standards are thus all technical regulations. The TBT Agreement imposes substantive requirements on technical regulations, namely that they be non-discriminatory and as non-trade restrictive as possible. For the purposes of this essay, however, the important provisions of the TBT Agreement are those relating to conformity assessment procedures, which are all “procedures used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled”.⁹³ These include, all “procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.”⁹⁴ Much like the SPS Agreement, the TBT Agreement requirement explicitly requires states to use conformity assessment procedures that treat imported products no less favorably than like domestic products.⁹⁵ Clearly, FDA’s import regime does not comply with this requirement. It thus violates the TBT Agreement as well as the SPS Agreement.

⁹²TBT Agreement 1.2, 1.5.

⁹³TBT Agreement Annex A(3).

⁹⁴*Id.*

⁹⁵TBT Agreement 5.1.1.

IV. Policy Recommendations and Conclusions

Although the FDA Import regime is clearly in violation of US obligations under the GATT, SPS Agreement, and TBT Agreement, that is no reason for alarm. First of all, the mere fact that a violation exists does not mean that a complaint will necessary be brought through the WTO dispute settlement process. Dispute resolution through the WTO is costly, and claims typically are brought only in cases of clear violations that harm discrete and powerful constituencies.⁹⁶ While food exporters might be this sort of constituency in many foreign countries, it would seem that they would have more to lose than they would to gain from pressing their governments to initiate WTO dispute resolution. Under the current regime, the vast majority of food imports are processed and enter the US without any FDA inspection, and as the statistics show, FDA's discriminatory import regime has not prevented an explosion in the amount of food imported into the US in the past ten years.⁹⁷ Assuming that WTO dispute resolution could actually force a change in FDA's policy, it is not clear that that change would actually favor foreign food exporters.⁹⁸ Additionally, given FDA's broad powers and discretion, and the solicitude that the agency is granted by US courts, foreign food producers would likely think twice before pressing their governments to take action that would antagonize FDA.

Even if dispute settlement proceedings are initiated under the WTO, and the end result is a judgment against the US, that does not mean that the FDA would be forced to abandon its food import regime. Basically, an adverse decision by a WTO Panel or the Appellate Body results in a request that the offending state bring

⁹⁶David G. Victor, *The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment After Five Years*, 32 N.Y.U. J. Int'l L. & Pol. 865,9 18-19 (2000).

⁹⁷See Part II, *supra*.

⁹⁸For instance, FDA could impose the Hazard Analysis and Critical Control Points (HACCP) system uniformly on all foreign and domestic food-processing plants. This system, which requires plants to follow specific procedures and keep detailed records to facilitate FDA inspection, might be a more onerous burden on foreign food producers than the current system which subjects 1-2% of imports to inspection. See Matthew Schaefer, *Sovereignty Revisited: Food Safety Regulations – Cross-border Implications – A US Perspective*, 24 Can.-U.S. L.J. 377, 379 (1998).

its measures into compliance with its WTO obligations. The WTO does not have any independent ability to enforce this request, however. If the offending state does not voluntarily comply with the decision, the aggrieved state may either seek alternative compensation from the violator, or seek authorization to punish the offender by withdrawing trade concessions.⁹⁹ As with compliance, compensation requires the cooperation of the party found to be in violation. The withdrawal of trade concessions is typically only effective if the withdrawing state actually has the ability to hurt the offending state by virtue of the withdrawal. In the case of the United States, because of the vast size of its economy, only major economic powers such as the European Union, Japan, and potentially the People's Republic of China can effectively use the withdrawal of trade concessions as a means of enforcing compliance with WTO obligations.¹⁰⁰ Even in the case of such retaliation, a truly determined state can decide to maintain its measure if it feels that the benefits of doing so exceed the costs imposed by the withdrawal of trade concessions.¹⁰¹ Although it is generally in the US interest to comply with adverse WTO rulings to preserve the legitimacy and integrity of a global trading system from which no country benefits more than the US, in this case the US should choose to pay compensation or endure retaliation rather than weaken FDA's ability to regulate imports. The safety of the American people is of paramount concern, and should not be sacrificed in the name of free trade.

That is not to say that FDA's current regime is perfect, or that the Agency should not seek to improve it, both in terms of its ability to assure the safety of imported foods, and in terms of its ability to expeditiously process safe imported food. FDA should continue to work to modernize and streamline its procedures to minimize the delay caused by its sampling and inspection activities. The computerized OASIS system was

⁹⁹DSU Art. 22.

¹⁰⁰This may change if developing states are successfully able to follow the precedent set by Ecuador in the *EU – Bananas* case. Ecuador was the first developing state to seek to use the withdrawal of concessions in the face of a refusal to comply with an Appellate Body ruling. Ecuador sought to withdraw concessions under the Trade Related Aspects of Intellectual Property Agreement (TRIPS), basically allowing it to retaliate against the EU's illegal quota system by refusing to recognize European copyrights and patents. This tactic is potentially a potent trade weapon for smaller states. See Benjamin L. Brimeyer, *Bananas, Beef, and Compliance in the World Trade Organization: The Inability of the WTO Dispute Settlement Process to Achieve Compliance From Superpower Nations*, 10 Minn. J. Global Trade 133, n.200. (2001).

¹⁰¹The EU, for example, has maintained its ban on the import of beef treated with hormones in the face of an adverse WTO ruling and US retaliation costing EU exporters more than \$120 million. See Brimeyer, *supra* n. 98 at 155-161.

an important step in this direction, and efforts should be made to expand OASIS to cover all imported foods. To the extent that its scarce resources permit, FDA should also try to expand its foreign inspection activities, taking advantage of the provision in the SPS Agreement that requires states to cooperate in such inspections.¹⁰²

Ultimately, however, FDA's scarce resources, in combination with the vast numbers of imports it must oversee, will require a different approach to the problem. FDA will need to rely increasingly on foreign regulatory systems to ensure the safety of food that is exported to the United States. To that end, FDA should work with appropriate foreign regulatory authorities to establish areas where foreign regulation can be accepted as equivalent to US regulation. Clearly this will not be appropriate in many cases. The US has one of the most stringent food safety schemes in the world, and many states, particularly in the developing world, are simply not capable of ensuring a comparable level of safety given their existing sanitary and regulatory infrastructure. Still, it seems likely that equivalence agreements could at least be worked out with the EU, Canada, and Japan. More limited agreements, perhaps relating to specific categories of food or food producers, could also be reached with other countries with which general equivalence agreements would not be appropriate. The primary mission of FDA will of course remain the protection of American consumers, so such agreements should only be reached when it is absolutely clear that the foreign regulatory apparatus will ensure the same overall level of food safety as would FDA. Accepting the equivalence of foreign regulations where appropriate will free up FDA resources, allowing the agency to devote more time and energy to monitoring imports from more problematic countries. Additionally, the states with which the US is likely to be able to reach equivalence agreements will tend to be its largest trading partners, and thus the states most likely to bring WTO dispute settlement proceedings against the US. Reaching equivalence agreements with those states will thus be likely to forestall any WTO action relating to FDA's import

¹⁰²SPS 4.1.

regime. Equivalence is not a panacea, however. It is potentially a useful way to ensure the safety of a large percentage of US food imports while conserving FDA resources, but FDA will need to maintain its current regime of essentially plenary regulatory authority over imports, both to deal with imports from states whose food safety standards are not equivalent, and as a back-up to catch unsafe products that slip through the cracks of equivalent foreign regulatory systems.